

§ 876.4300

§ 876.4300 Endoscopic electrosurgical unit and accessories.

(a) *Identification.* An endoscopic electrosurgical unit and accessories is a device used to perform electrosurgical procedures through an endoscope. This generic type of device includes the electrosurgical generator, patient plate, electric biopsy forceps, electrode, flexible snare, electrosurgical alarm system, electrosurgical power supply unit, electrical clamp, self-opening rigid snare, flexible suction coagulator electrode, patient return wristlet, contact jelly, adaptor to the cord for transurethral surgical instruments, the electric cord for transurethral surgical instruments, and the transurethral desiccator.

(b) *Classification.* Class II (performance standards).

§ 876.4370 Gastroenterology-urology evacuator.

(a) *Identification.* A gastroenterology-urology evacuator is a device used to remove debris and fluids during gastroenterological and urological procedures by drainage, aspiration, or irrigation. This generic type of device includes the fluid evacuator system, manually powered bladder evacuator, and the AC-powered vacuum pump.

(b) *Classification.* (1) Class II (special controls) for the gastroenterology-urology evacuator when other than manually powered. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

(2) Class I for the gastroenterology-urology evacuator when manually powered. The device subject to this paragraph (b)(2) is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[48 FR 53023, Nov. 23, 1983, as amended at 54 FR 25049, June 12, 1989; 63 FR 59228, Nov. 3, 1998]

§ 876.4400 Hemorrhoidal ligator.

(a) *Identification.* A hemorrhoidal ligator is a device used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or band placed around the hemorrhoid.

(b) *Classification.* Class II (performance standards).

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§ 876.4480 Electrohydraulic lithotripter.

(a) *Identification.* An electrohydraulic lithotripter is an AC-powered device used to fragment urinary bladder stones. It consists of a high voltage source connected by a cable to a bipolar electrode that is introduced into the urinary bladder through a cystoscope. The electrode is held against the stone in a water-filled bladder and repeated electrical discharges between the two poles of the electrode cause electrohydraulic shock waves which disintegrate the stone.

(b) *Classification.* Class II. The special control for this device is FDA's "Guidance for the Content of Premarket Notifications for Intracorporeal Lithotripters."

[48 FR 53023, Nov. 23, 1983, as amended at 52 FR 17738, May 11, 1987; 65 FR 17145, Mar. 31, 2000]

§ 876.4500 Mechanical lithotripter.

(a) *Identification.* A mechanical lithotripter is a device with steel jaws that is inserted into the urinary bladder through the urethra to grasp and crush bladder stones.

(b) *Classification.* Class II (performance standards).

§ 876.4530 Gastroenterology-urology fiberoptic retractor.

(a) *Identification.* A gastroenterology-urology fiberoptic retractor is a device that consists of a mechanical retractor with a fiberoptic light system that is used to illuminate deep surgical sites.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 54 FR 25049, June 12, 1989; 66 FR 38801, July 25, 2001]

§ 876.4560 Ribdam.

(a) *Identification.* A ribdam is a device that consists of a broad strip of latex with supporting ribs used to drain surgical wounds where copious urine drainage is expected.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in